

REMARKS

Reconsideration of the present application is respectfully requested. Applicant would like to thank Examiner Osinski for the courtesies extended to Applicant's representative in the phone discussion wherein it was pointed out to the Examiner that there is an error in the file record for the present application. That is, the claims of a preliminary amendment, filed May 23, 2006, were entered into the present application in error.

It is believed that the noted discrepancy is due to claims for Application Serial No. 10/502,321 (believed to correspond to US Pub 2005/0152993 to De Oliveira) being improperly submitted by the Applicant in that case to the present case. A review of the record, and particularly the cover sheet of the May 23, 2006 preliminary amendment, shows that while that preliminary amendment designated the present Application's Serial No. 10/502,231, all the remainder of the information in that cover sheet references a different application. Accordingly it is clear that the Applicant in that case made an error in its serial number designation and that error has led to that preliminary amendment being improperly entered into this '231 application. A review of the subject matter of the claims in the May 23, 2006 further reveals that those claims have no direct relationship to the subject matter of the present application.

Also, this filing error by the Applicant in the '321 application has led to the publication of this '231 application with an incorrect set of claims. Accordingly, as Applicant had no role in this error on the part of the '321 Applicant and the USPTO in filing and entering an incorrect set of claims, Applicant is filing under separate cover a request for republication of the present application with the correct claim set (e.g., the claim set as originally filed in the present case).

Also, based on the Office Action, it is considered that Examiner Osinski properly examined the claims as filed in the present case and which correspond with Applicant's previously filed PCT Application, PCT/GB03/00287) and not the claims presented in the improper preliminary amendment discussed above. The claim amendments herein have been made to the original claims filed in this application and not the improperly entered set. (It is presumed the Office will properly expunge from the record the incorrectly entered Preliminary Amendment).

The Office Action dated April 8, 2008 has been received and its contents carefully noted. Claims 1-19 were pending at the time of the Examiner's consideration.

By this response, claim 19 has been cancelled. Claims 4, 10, 12, 16, 17 and 18 have been amended. Namely, claims 4, 10, 12, 16 and 17 have deleted multiple dependencies. New claims 20 and 21 have been added. As the claim amendment made to 4, 10, 12, 16 and 17 (and 20, 21 – recapturing of some of the subject matter presented in original multiple dependent claim 4) are all directed at removing an objectionable multiple dependency format and to avoid the fees associated with the same, they are submitted not directed at an amendment on the merits or a rejection raised by the Examiner. Further, claim 18 has been amended to recite the use of the apparatus of claim 5 in a manner covered in the original application. Thus, no statutory new matter has been added since support for all claim amendments can be found in the originally filed disclosure.

Drawings

An objection was made to the Drawings as failing to comply with 37 CFR 1.84(p)(5) because reference characters 10 and 153 were considered by the Examiner to be absent in the description. In response, Applicant contends that reference character 10 is provided on paragraph 12 of the disclosure as a “Drive Unit” and reference character 153 is provided on paragraph 15 of the disclosure as a “Swirl Chamber”.

An objection was also made to figure 1 for failing to show dispensing device 140 as described in the specification. As such, Applicant has provided an amended “replacement” drawing sheet referencing element 140. No new matter is considered presented with this drawing amendment as the original disclosure indicates reference number 140 and the location relative to the original drawing filed. Accordingly, Applicant respectfully requests withdrawal and reconsideration of the objections, *supra*.

Specification

An objection to the Drawings was made for failing to comply with 37 CFR 1.84(p)(4) because reference characters 149 and 150 were considered to have been used to designate both nozzle and nested components and inner and outer components. In response, Applicant believe that all references to the components designated 149 and 150 in the specification are clear (e.g., one of ordinary skill in the art with the benefit of the original disclosure would understand what

is being referred to in each instance). However, the specification has been amended to have the order of “outer” and “inner” better coincide with the reference designations of “149” and “150” following said designations to facilitate a more rapid referencing by a reader of the specification. Based on the foregoing withdrawal of the drawing objection relative to reference numbers 149 and 150 is respectfully requested.

Additionally, the Title of the Invention was noted as being considered not as descriptive as desired by the Examiner. Accordingly, Applicant accepts the suggested title presented in the Office Action, “Dispensing Device with Agitations of Dispensing Fluid”. In view of the amendments to the Specification, *supra*, Applicant respectfully solicits withdrawal and reconsideration of the objection.

Claim Rejections – 35 USC § 112/101

Claim 18 stands rejected under 35 USC 112 and 101 as being deemed indefinite for reciting a use without any active, positive steps delimiting how this use is actually practiced. In response, Applicant has amended claim 18 in accordance with MPEP 2173.05(q) to be in accord with the criteria of 35 USC 112 and 101, and thus withdrawal of the rejection relative to claim 18 is respectfully requested.

Claim 19 stands rejected under 35 USC 112 for failing to particularly point out what is included or excluded by the claim language. The rejection to claim 19 is moot as directed to cancelled subject matter.

Rejections Under 35 USC § 103(a)

Claims 1-17 stand rejected as being unpatentable over Haber et al (US 5,211,285) in view of Lilley et al (US 5,891,085). The rejection as to claims 1-17 is traversed. Applicant respectfully solicits withdrawal and reconsideration of the rejection in view of the claim amendments and arguments presented herein.

Applicant respectfully submits that Haber in view of Lilley does not disclose the Applicant’s independent method claim 1 feature of

“a) increasing the volume of the reservoir above an initial volume so as to reduce the pressure in the reservoir to below atmospheric;”

In similar fashion, Applicant respectfully submits that Haber in view of Lilley does not disclose the Applicant's independent apparatus claim 5 feature of –

“means for creating at least a partial vacuum in the reservoir of liquid suspension”

In the Office Action there is asserted that Haber is considered to provides all of the limitations of the claimed invention but does not expressly disclose the original pressure inside the reservoir being atmospheric. It is respectfully submitted that Haber, in addition to having the deficiency that led to the inclusion of Lilley in the obviousness rejection, also fails to disclosure the above quoted features of the noted independent claims 1 and 5.

That is, it is respectfully submitted that Haber does not disclose a method step of increasing the volume of the reservoir above an initial volume so as to reduce the pressure in the reservoir to below atmospheric prior to agitation (method claim 1) or “means for creating at least a partial vacuum in the reservoir of liquid suspension”

In the Office Action there is set forth the following:

“a. Regarding claims 1 and 5, Haber et al discloses an apparatus and method of use with a reservoir 4 that is normally isolated from the atmosphere A (Figure 1). The volume of a first reservoir 34 my [by] pushing on inner container 6. From figure 2 it is apparent the volume of the reservoir becomes larger. The pressure falling as the volume increases in an inherent feature of a closed, non-reactive system.”

A review of Haber reveals that outer container 4 contains the pharmaceutical product 38 within volume portion 34 with uncompressed gas contained in the inner space 20 of inner container 6 (Figure 1) slidingly received within the outer container 4. Figure 2 further shows a compression of the top septum end and a compression of the lower end of inner container 6 toward one another. During this compression piston cap 26 allows free flow of the pharmaceutical product into the upper interior of inner container 6 as the inner container moves up (and hence the Figure 2 septum is shown adjusted down relative to its original position shown in Figure 1- although for comparison purposes a common septum level maintenance for all

figures is more informative relative to the common volume occupation assumed by the system's containment volume relative to the incompressible liquid). That is, as the pharmaceutical product is considered incompressible, the volume occupied by the pharmaceutical product stays the same and is always maintained at least at its original pressure if not greater as the piston 22 bias level on the pharmaceutical product is actually increased by the upward bias force produced by the compressing gas in the outer portion of the inner container as the inner container slides upward into the outer container and past the piston 22.

In fact, if anything, there is an effort by the system shown in Haber to reduce, and not increase the volume, made available by the system to hold the pharmaceutical product as Haber's system is designed to increase in pressure below the illustrated piston during the adjustment shown by a comparison of Figures 1 and 2 (although the incompressible nature of the pharmaceutical product would work to preclude such a reduction in volume). Further, it is this compressed gas which then works to draw back the inner container and thus pull down the piston cap relative to a stationary piston 22 back to its original state (i.e., it is the inner container that is shown adjusting relative to the piston 22 and at no time does the volume that is defined by the system to hold the pharmaceutical product increase as can be expected due to the incompressible nature of the pharmaceutical product).

Accordingly, the arrangement presented in Haber does not provide the claim 1 method step of –

“a) increasing the volume of the reservoir above an initial volume so as to reduce the pressure in the reservoir to below atmospheric;”

Further since there is no reduction in volume relative to the system confining the pharmaceutical product there is further lacking the possibility of reducing the pressure in the reservoir to below atmospheric. Thus, the disclosure of Lilley fails to remedy this deficiency in Haber relative to the claim 1 method.

Further, the same discussion applied above relative to method claim 1 is applicable to the feature of claim 5 which reads: "means for creating at least a partial vacuum in the reservoir of liquid suspension". In other words, the system shown in Haber is not of the type that provides for a creation of a partial vacuum, and, in fact, works in an opposite direction of attempting to reduce the volume provided for holding of the liquid as the compression behind the piston increases as inner vial moves further inward into the outer container while sliding past the piston.

Accordingly, it is respectfully submitted that independent claims 1 and 5 stand in condition for allowance relative to the applied references in the Office Action. Also, as all remaining claims depend from claims 1 and 5, they too are submitted to be in condition for allowance.

CONCLUSION

Accordingly, it is respectfully submitted that the application stands in condition for allowance and favorable reconsideration is earnestly solicited.

If any fees are due in connection with the filing of this Amendment, such as fees under 37 C.F.R. §§1.16 or 1.17, please charge the fees to Deposit Account 02-4300; Order No. 033335R046.

Respectfully submitted,
SMITH, GAMBRELL & RUSSELL, LLP

By: 

Dennis C. Rodgers, Reg. No. 32,936
1130 Connecticut Avenue, N.W., Suite 1130
Washington, DC 20036
Telephone: 202/263-4300
Facsimile: 202/263-4329

Date: July 8, 2008